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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/698,929

10/31/2003

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ACSC 64781 (4150P)

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EXAMINER

OMGBA, ESSAMA

ART UNIT

PAPER NUMBER

3726

MAIL DATE

DELIVERY MODE

02/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/698,929	Applicant(s) KOKISH ET AL.	
	Examiner Essama Omgba	Art Unit 3726	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 is/are allowed.
- 6) ☒ Claim(s) 1,4-7 and 9-15 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The indicated allowability of claims 3-6 is withdrawn in view of the reference(s) to Gonzales et al. (US Patent 6,683,757). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 4-7 and 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzales et al. (US Patent 6,863,757).

With regards to claims 1, 4-6 and 13, Gonzales et al. discloses a method of making a polymeric tubular layer of an expandable medical device or component comprising placing a polymeric tubular layer 10 having a length in a lumen of a tube 14, the polymeric tubular layer in the lumen disposed on a mandrel 12 (fig. 3A), longitudinally stretching the tube to a stretch configuration and restraining the tube in the stretched configuration (col. 6, lines 24-32 and 49-53), unrestraining the tube to release the tube from the stretched configuration so that the length of the tube decreases and thereby longitudinally compresses the polymeric tubular layer, detaching the tube from the compressed polymeric tubular layer and removing the compressed tubular layer from the lumen of the tube and from the mandrel, to form the polymeric

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tubular layer of the expanded medical device (col. 2, lines 49-53 and col. 6, lines 56-61). Although Gonzales et al. discloses using heat shrinking in making the polymeric tubular layer instead of having the tube and the polymeric tubular layer therein in a housing and exposing the tube with the polymeric layer therein to a pressurized fluid introduced into the housing to thereby apply the radially inward force to the tube, however it would have been obvious to one of ordinary skill in the art at the time of the invention that having the tube and the polymeric tubular layer therein in a housing and exposing the tube with the polymeric layer therein to a pressurized fluid introduced into the housing to thereby apply the radially inward force to the tube is an obvious matter of design choice wherein no stated problem is solved or unexpected results obtained in having the tube and the polymeric tubular layer therein in a housing and exposing the tube with the polymeric layer therein to a pressurized fluid introduced into the housing to thereby apply the radially inward force to the tube versus using heat shrinking as disclosed by Gonzales et al. Applicant should note that the tube is attached in the stretched configuration to the polymeric tubular layer when the tube is heated and radially shrinks. Also the invention as disclosed by Gonzales et al. could be used for making a catheter having a balloon (col. 2, lines 53-56 and col. 9, lines 27-30). Applicant should also note that a radially inward force is provided to the tube as a result of heat shrinking in the radial direction.

With regards to claim 7, Gonzales et al. discloses a method of making a polymeric tubular layer of an expanded medical device as shown above. Although Gonzales et al. does not specifically disclose the elastomer polymer tube being stretched at least about 120%, however Gonzales et al. discloses that the polymeric

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tube can be stretched by a specific amount to provide a heat shrink tube which axially shrinks by a desired amount (col. 3, lines 29-33). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided such stretching percentage in the method of Gonzales et al., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art.

For claim 9, Applicant should note that it is within the general knowledge of one of ordinary in the art to repeat the method steps as needed in order to achieve a desired compaction of the tubular layer.

For claim 10, see column 7, lines 4-6.

For claims 11 and 14, see column 8, lines 54-58.

For claim 12, Applicant should note such recited steps are conventional in the art.

For claim 15, see column 2, lines 47-49.

Allowable Subject Matter

4. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Claim 16 is allowed.

Response to Arguments

6. Applicant's arguments with respect to claims 1, 4-7 and 9-15 have been considered but are moot in view of the new ground(s) of rejection.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Essama Omgba whose telephone number is (571) 272-4532. The examiner can normally be reached on M-F 9-6:30, 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Bryant can be reached on (571) 272-4526. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Essama Omgba/
Primary Examiner, Art Unit 3726

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February 15, 2008